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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,714	12/28/2001	Bernhard Eistert	KEIL/149/PC/US	1040

2543 7590 04/04/2003

ALIX YALE & RISTAS LLP  
750 MAIN STREET  
SUITE 1400  
HARTFORD, CT 06103

EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/019,714

Applicant(s)

Eistert

Examiner  
Joseph Weiss

Art Unit  
3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 28, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 2-20 are objected to because of the following informalities: Use of the article "The" at the beginning of each claim is more grammatically accurate. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 1 recites the limitation "the tracheal cross sectional area" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 1 recites the limitation "the section of the shaft above the cuff" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

In regards to claim 1, line 5 what is "This"?

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Psaros (US 5765558).

In regards to claim 1, Psaros discloses a tracheal cannula (note fig 7) having a shaft (2) and a cuff (6) for blocking the tracheal cross sectional area surrounding the shaft such that a section of the shaft above the cuff has a window (44) that is covered by an air permeable membrane (46).

In regards to claim 2, the membrane of Psaros is made of gas permeable TEFLON, such micro-porous materials are inherently liquid water impermeable. (See e.g. US 5177996, see also TESS Reg. # 1111147)(col. 4 lines 40-45)

In regards to claim 3, Psaros discloses the membrane consisting essentially of PTFE.(col. 4 lines 40-45)

In regards to claim 4, Psaros discloses the membrane comprising PTFE.(col. 4 lines 40-45).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros.

In regards to claims 5 & 6, Psaros substantially discloses the claimed invention except for the use of "laced" or woven PTFE as the membrane material, a.k.a. Goretex.

It is noted that applicant's specification does not set forth the use of woven PTFE, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary. See e.g. 4921642

10. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros as applied to claims 1-6 above, and further in view of Muir (US 4759356).

In regards to claims 7-12, Psaros substantially discloses the instant application's claimed invention, but does not explicitly disclose a valve that opens upon inhalation & closes upon exhalation at the entrance of the cannula. However, Muir disclose such (10). The references are

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analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Muir and used them with the device of Psaros. The suggestion/motivation for doing so would have been to permit the patient to have improved speech while tracheotomized (Note abstract & Summary of invention). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

11. Claims 13-18 & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros as applied to claims 1-6 above, and further in view of Abel (US 5056515).

In regards to claim 13-18, Psaros substantially discloses the instant application's claimed invention, but does not explicitly disclose the cuff connected via a line to a balloon means for inflation of the cuff and controlling cuff pressure. However, Abel disclose such (line 68, balloon means 70). The references are analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Abel and used them with the device of Psaros. The suggestion/motivation for doing so would have been to insure optimal

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fit of the cuff to the user's trachea without damage to the tracheal tissue. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 20, the suggested device discloses the balloon means as a pilot balloon. (See Abel 70).

12. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros & Muir as applied to claim 7 above, and further in view of Abel (US 5056515).

In regards to claim 7, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the cuff connected via a line to a balloon means for inflation of the cuff and controlling cuff pressure. However, Abel disclose such (line 68, balloon means 70). The references are analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Abel and used them with the suggested device. The suggestion/motivation for doing so would have been to insure optimal fit of the cuff to the user's trachea without damage to the tracheal tissue. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

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Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

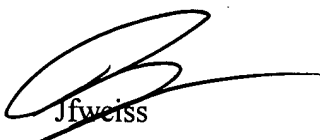
***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6135111, 6039696, 5964221, 5957978, 5419314, 5392775, 5177996, 4921642, 4852565, 4794924, 4751924, 4627433, 4573460, 4538607, 4459984, 4037605

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



Jfweiss

March 25, 2003



WEILUN LO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700